



HEALTH INDUSTRY GROUP PURCHASING ASSOCIATION



August 4, 2005

Lester M. Crawford, DVM, Ph.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Re: Bar Code Label Requirement for Human Drug Products and Biological Products; (69 Federal Register 9120) February 26, 2004 (Docket No. 2005D-0202)

Dear Dr. Crawford:

I write on behalf of the Health Industry Group Purchasing Association ("HIGPA") to comment on the Food and Drug Administrations draft guidance regarding "Guidance for Industry: Bar Code Label Requirements—Question and Answers."

HIGPA is a broad-based trade association representing health care group purchasing organizations (GPOs) and includes in its membership trading partners, such as distributors, manufacturers, wholesalers, who represent the supply-side (non-labor) of the hospital, nursing home and other health care provider organizations. HIGPA's GPO members include for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and health care provider alliances.

HIGPA members are concerned with FDA's language concerning compliance with the April 26, 2006 effective date of the bar code rule. Confusion in the health care industry exists regarding the loose definition of manufacturer "compliance" as outlined by the FDA. Compliance could be interpreted two different ways. Either the FDA requires manufacturers to have bar code labeling on all targeted pharmaceuticals that are shipped as of the effective date or applied to those products packaged as of the effective date.

Health care providers are best served if compliance is based upon the ship date. For example, a manufacturer could produce a lot of a specific product on April 1, 2006 sufficient to supply the marketplace for a six-month period. It is conceivable that it could take nine to 12 months before there would be a consistent supply of bar code labeled product available to the provider. This will create significant confusion in the marketplace regarding which generic products to purchase for those facilities that have either already or are considering implementation of a bedside bar code scanning process. Many of these facilities have been waiting for the April 26, 2006



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effective date to ensure that properly labeled products are available. Importantly, the bar code rule was implemented as part of an effort to enhance patient safety. An interpretation based on package date only extends the opportunity for more adverse patient events.

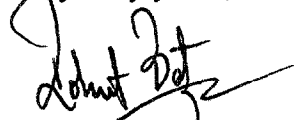
To date there is no commercial database available to identify which products have labeling with approved bar code formats. Additionally, it is unlikely that an existing database would add this product attribute to any existing database since it is an issue only for the implementation period. It would also be very difficult to maintain an accurate bar code status as bar code labeling is implemented by manufacturers. Providers would be required to contact manufacturers and wholesalers for each specific SKU (stock keeping unit) to determine bar code labeling status.

An interpretation now by the FDA to define compliance to products packaged, rather than products shipped, on or after April 26, 2006 effectively extends the ramp up period beyond the two years as previously provided in the rule. It is also important to note it will still take several months to deplete inventory stock of products without bar code labeling on the shelves at the many wholesaler and manufacturer distribution centers even if the requirement states that products shipped as of April 26, 2006 must comply with the rule.

An official restatement of the terms of compliance, clarifying that all products shipped on/after April 26, 2006 must contain bar codes would be most helpful to ensure the bar code rule is properly implemented by the manufacturing community and ultimately benefits health care providers in a timely fashion.

Thank you for your consideration. If I can be of assistance to you in the future, please contact me at (703) 243-9262 or at rbetz@higpa.org.

Very truly yours,



Robert Betz, Ph.D.
President and CEO

cc: HIGPA Board of Directors